

General

Guideline Title

Pediatric hydrocephalus: systematic literature review and evidence-based guidelines. Part 5: effect of valve type on cerebrospinal fluid shunt efficacy.

Bibliographic Source(s)

Baird LC, Mazzola CA, Auguste KI, Klimo P Jr, Flannery AM. Pediatric hydrocephalus: systematic literature review and evidence-based guidelines. Part 5: Effect of valve type on cerebrospinal fluid shunt efficacy. J Neurosurg Pediatr. 2014 Nov;14 Suppl 1:35-43. [44 references]
[PubMed](#)

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The rating schemes used for the strength of the evidence (Class I-III) and the levels of recommendations (Level I-III) are defined at the end of the "Major Recommendations" field.

Recommendations

- There is insufficient evidence to demonstrate an advantage of one shunt hardware design over another for the treatment of pediatric hydrocephalus. Current designs described in the evidentiary tables (see the original guideline document) are all treatment options. Strength of Recommendation: Level I, high degree of clinical certainty.
- There is insufficient evidence to recommend the use of a programmable valve versus a nonprogrammable valve. Programmable and nonprogrammable valves are both options for the treatment of pediatric hydrocephalus. Strength of Recommendation: Level II, moderate degree of clinical certainty.

Definitions

Levels of Evidence for Primary Research Question¹

	Therapeutic Studies: Investigating the Results of Treatment	Prognostic Studies: Investigating the Effect of a Patient Characteristic on the Outcome of Disease	Diagnostic Studies: Investigating a Diagnostic Test	Economic and Decision Analyses: Developing an Economic or Decision Model
Class I	<ul style="list-style-type: none"> High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals Systematic review² of Class I RCTs (and study results were homogenous³) 	<ul style="list-style-type: none"> High quality prospective study⁴ (all patients were enrolled at the same point in their disease with $\geq 80\%$ follow-up of enrolled patients) Systematic review² of Class I studies 	<ul style="list-style-type: none"> Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) Systematic review² of Class I studies 	<ul style="list-style-type: none"> Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses Systematic review² of Class I studies
Class II	<ul style="list-style-type: none"> Lesser quality RCT (e.g., $<80\%$ follow-up, no blinding, or improper randomization) Prospective⁴ comparative study⁵ Systematic review² of Class II studies or Class I studies with inconsistent results Case control study⁷ Retrospective⁶ comparative study⁵ Systematic review² of Class II studies 	<ul style="list-style-type: none"> Retrospective⁶ study Untreated controls from an RCT Lesser quality prospective study (e.g., patients enrolled at different points in their disease or $<80\%$ follow-up) Systematic review² of Class II studies Case control study⁷ 	<ul style="list-style-type: none"> Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) Systematic review² of Class II studies Study of nonconsecutive patients; without consistently applied "gold" standard Systematic review² of Class III studies 	<ul style="list-style-type: none"> Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses Systematic review² of Level II studies Analyses based on limited alternatives and costs; and poor estimates Systematic review² of Level III studies
Class III	<ul style="list-style-type: none"> Case series⁸ Expert opinion 	<ul style="list-style-type: none"> Case series Expert opinion 	<ul style="list-style-type: none"> Case control study Poor reference standard Expert opinion 	<ul style="list-style-type: none"> Analyses with no sensitivity analyses Expert opinion

RCT = randomized controlled trial

¹A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

²A combination of results from two or more prior studies.

³Studies provided consistent results.

⁴Study was started before the first patient enrolled.

⁵Patients treated one way (e.g., cemented hip arthroplasty) compared with a group of patients treated in another way (e.g., uncemented hip arthroplasty) at the same institution.

⁶The study was started after the first patient enrolled.

⁷Patients identified for the study based on their outcome, called "cases" (e.g., failed total arthroplasty) are compared to those who did not have outcome, called "controls" (e.g., successful total hip arthroplasty).

⁸Patients treated one way with no comparison group of patients treated in another way.

Strength of the Recommendations Rating Scheme

The Task Force used methodologies endorsed by the American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (CNS) Guidelines Committee to assign a strength category to each recommendation in this review. Linking evidence to recommendations through the use of evidentiary tables has been endorsed by the American Medical Association, the AANS, and the CNS. This process validates and supports the relationship between the strength of evidence and the strength of recommendations. Demonstrating the highest degree of clinical certainty, Class I evidence is used to support recommendations of the strongest type, defined as Level I recommendations. Level II recommendations reflect a moderate degree of clinical certainty and are supported by Class II evidence or a strong consensus of Class III evidence. Level III recommendations denote clinical uncertainty, which is supported by inconclusive or conflicting evidence or expert opinion.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Pediatric hydrocephalus

Guideline Category

Management

Treatment

Clinical Specialty

Neurological Surgery

Neurology

Pediatrics

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To examine the existing literature to compare differing shunt components used to treat hydrocephalus in children, find whether there is a superior shunt design for the treatment of pediatric hydrocephalus, and make evidence-based recommendations for the selection of shunt implants when placing shunts

Target Population

Pediatric patients with hydrocephalus

Interventions and Practices Considered

Consideration of various shunt hardware design (differing shunt components, mechanisms, or valve design), including all types of standard differential pressure valves, valves with an antisiphon mechanism, and programmable valves

Note: There was insufficient evidence to demonstrate an advantage for one shunt hardware design over another or to recommend the use of a programmable valve versus a nonprogrammable valve.

Major Outcomes Considered

- Shunt survival
- Shunt complications
- Development of slit ventricle syndrome
- Development of signs or symptoms of overdrainage

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

General Search Strategy

Literature Search

The Task Force worked with a research librarian and methodologist to assist with the formulation of search terms and strategies used to search the US National Library of Medicine PubMed/MEDLINE database and the Cochrane Database of Systematic Reviews for relevant literature published between January 1966 and March 2012.

Four to five Task Force members used the article inclusion/exclusion criteria described below to screen abstracts and provide a list of relevant articles for a full-text review. Each Task Force member was blinded to the lists of abstracts provided by others. Staff compiled all lists together for review and final approval by all Task Force members.

The searches were supplemented with manual screenings of bibliographies from all retrieved articles. In addition, the bibliographies of potentially relevant systematic reviews were screened for potentially relevant articles. All literature identified either by searches of the electronic database or by manual searches were subject to the article inclusion/exclusion criteria listed below. Specific search strategies used by Task Force members are provided below.

Article Inclusion/Exclusion Criteria

Articles were retrieved and included as evidence to support the topics discussed in this review if they met specific inclusion/exclusion criteria. These criteria were also applied to articles provided by Task Force members who supplemented the electronic database searches with articles obtained from manual searches of bibliographies from the original articles. To reduce bias, the criteria were specified before conducting the literature searches. For the purposes of the systematic review and guidelines, articles that did not meet the following criteria were *not* deemed evidence and were not considered as potential evidence to support the topics and clinical recommendations.

To be included in the review, an article had to meet the following criteria:

- Studies that combined results in patients (younger than 18 years of age) who had congenital and acquired hydrocephalus with results in patients with "normal" pressure hydrocephalus were excluded if the study enrolled fewer than 80% of the target patient population.

- Studies that enrolled mixed patient populations were included only if separate results were reported for the target population. The results of the target population were the only results considered as evidence to support the recommendations.
- The study was a full article report of a clinical study.
- The study was not a meeting abstract, editorial, letter, or a commentary.
- Prospective case series had to report baseline values.
- Case series studies with nonconsecutive enrollment of patients were excluded.
- Studies had to have appeared in a peer-reviewed publication or a registry report.
- Studies had to enroll at least 10 patients for each distinct outcome that was measured. If a comparative study, a minimum enrollment of five patients per treatment arm for each outcome was necessary.
- The study involved humans.
- The study was published in or after 1966.
- The study presented results quantitatively.
- The study did not involve "in vitro" or "biomechanical" data or results obtained in cadavers.
- The study was published in English.
- Papers reporting the results of systematic reviews, meta-analyses, or guidelines developed by others were excluded.

Articles presenting systematic reviews or meta-analyses conducted by others, as well as guidelines developed by others, were not included as evidence to support this review due to differences in inclusion/exclusion criteria between those specified in such articles and those established by the Task Force. Although such articles were not included as evidence to support the review, they were recalled for full-text review so that the Task Force could conduct manual searches of the articles' bibliographies.

Specific Search Strategy for This Guideline

Search Criteria

The US National Library of Medicine (PubMed/MEDLINE) and the Cochrane Database of Systematic Reviews were queried for the period January 1966 through March 2012 using medical subject headings (MeSH) and key words relevant to shunt system components as detailed below.

Search Terms

PubMed/MEDLINE

1. ("Cerebrospinal Fluid Shunts"[MeSH]) "Hydrocephalus"[MeSH:noexp]
2. 1 AND (programmable OR nonprogrammable OR non-programmable OR siphon OR antisiphon* OR anti-siphon* OR ("differential pressure" OR "fixed pressure") OR valve*)
3. Limit 2 to Child (0–18 years)
4. Limit to English and Humans

Cochrane Database

1. MeSH descriptor Child
2. MeSH descriptor Infant
3. 1 or 2 and (MeSH descriptor Cerebrospinal Fluid Shunts)
4. 3 and (MeSH descriptor Hydrocephalus)
5. (programmable OR nonprogrammable)
6. 4 and 5

Search Results

The search yielded 269 abstracts, which were then reviewed for relevance to the demonstration of superiority of 1 shunt component over another. Forty-three articles were recalled for full-text review. Predetermined inclusion and exclusion criteria were used to review each of these articles in detail. Twenty-two articles were included in the final evidentiary table. Reasons for exclusion of full-text articles included the absence of a valid comparison group (n=14), the absence of a valid outcome variable (n=4), invalid study design (n=2), and redundant patient population (n=1) (see Figure 1 in the original guideline document).

Number of Source Documents

Twenty-two articles (1 Class I study, 11 Class II studies, and 10 Class III studies) were included in the final evidentiary table. Also see Figure 1 in the original guideline for the flowchart showing the process involved in identifying relevant literature.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Levels of Evidence for Primary Research Question¹

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⁸Patients treated one way with no comparison group of patients treated in another way.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The quality of evidence was rated using an evidence hierarchy developed by the American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (CNS) Guidelines Committee for each of the four different study types: therapeutic, diagnostic, prognostic, and clinical assessment (see the "Rating Scheme for the Strength of the Evidence" field).

For each article included in the evidentiary table, the study type, summary findings, and major conclusions were recorded, and a preliminary data class was assigned. The Pediatric Hydrocephalus Systematic Review and Evidence-Based Guidelines Task Force met to discuss the ranking of the evidence and the classification of data. Recommendations were then made based on the strength of the data in the evidentiary table (see Table 1 in the original guideline document).

Methods Used to Formulate the Recommendations

Expert Consensus (Nominal Group Technique)

Description of Methods Used to Formulate the Recommendations

The recommendations contained in this guideline deliberately eschew the use of expert opinion, relying strictly on information available in the literature. Studies have reported that expert opinions may not use evaluable evidence, if the papers containing that evidence do not support the "expert" point of view. Throughout the development of these guidelines, the Task Force used evidence-based methodologies and adhered to strict criteria that had been defined a priori as specified by the Institute of Medicine's standards for conducting systematic reviews and clinical evidence-based guidelines.

This effort was begun by a small study group that convened at the Pediatric Section Annual Meeting in Austin, Texas, in 2011. At that time the basic topics were considered, and over the course of several months these were further refined. Members of the Task Force involved in the creation of this document were recruited from a variety of institutions and subspecialty disciplines in an effort to have as broad a representation of opinions and expertise as possible.

The Task Force followed protocols established by the Joint Guidelines Committee (JGC) of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS). A conscientious effort was also made to be sure that conflict of interest was avoided. Members who had published extensively in certain areas were mindfully assigned to evaluate evidence in other topics. Every effort was made to ensure that the work product would be transparent and trustworthy.

Methods

Process Overview

The Task Force and the Pediatric Section of the AANS/CNS conducted a systematic review of the literature relevant to the management of hydrocephalus in infants and children. Additional details of the systematic review are provided below. During the development process, the panel participated in a series of conference calls and meetings. Multiple iterations of the written review were conducted by individuals in the Task Force

and various AANS/CNS committees.

Selection of Clinical Topics

The goals of this effort were to discern the most effective strategies for a variety of hydrocephalus-related problems, including acquired hydrocephalus of the premature neonate. The Task Force also considered the use of technical adjuvants such as antibiotic-impregnated catheters, endoscopic placement of shunt catheters, electromagnetic guidance for shunt catheter placement, and ultrasound guidance for shunt catheter placement. It was hoped that these adjuvants would lead to improvements in outcome and a reduction in the frequency of revision.

Complications associated with ventriculoperitoneal shunts and endoscopic third ventriculostomies are known, and these interventions' effects and long-term successes are useful to evaluate. Complications associated with infection are of particular significance. Therefore, the prevention and treatment of infection occupies a significant portion of the hydrocephalus literature. Finally, the correlation of ventricle size to outcome in a child is a source of great interest as an indicator of the success of the intervention.

Following the identification of hydrocephalus-related problems, the Task Force developed preliminary recommendations that were formatted similarly to the PICO (patients, interventions, comparisons, and outcomes) formula to aid in the determination of the overall scope of the review and the terminology used to formulate the literature search strategies.

Voting on the Recommendations

The Task Force used a structured voting technique to finalize and approve the final recommendations, language, and strength of the recommendations presented in this review. The voting technique is referred to as the "nominal group technique." This technique includes up to 3 rounds of voting using secret ballots to ensure that each Task Force member is blinded to the responses of other Task Force members. All the recommendations in this review were approved following the first round of voting and no further discussion was needed to finalize the recommendations. During the course of editing and finalizing the document, changes were made to allow recommendations to conform to the rules of evidence and language as described earlier. When this occurred, the changes were reviewed and approved by the group.

See Fig. 1 in the methodology document (see the "Availability of Companion Documents" field) for an outline of the key steps in the process of developing these clinical practice guidelines.

Rating Scheme for the Strength of the Recommendations

Strength of the Recommendations Rating Scheme

The Task Force used methodologies endorsed by the American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (CNS) Guidelines Committee to assign a strength category to each recommendation in this review. Linking evidence to recommendations through the use of evidentiary tables has been endorsed by the American Medical Association, the AANS, and the CNS. This process validates and supports the relationship between the strength of evidence and the strength of recommendations. Demonstrating the highest degree of clinical certainty, Class I evidence is used to support recommendations of the strongest type, defined as Level I recommendations. Level II recommendations reflect a moderate degree of clinical certainty and are supported by Class II evidence or a strong consensus of Class III evidence. Level III recommendations denote clinical uncertainty, which is supported by inconclusive or conflicting evidence or expert opinion.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Guideline Panel Consensus and Practice Guideline Approval Process

Topic subtask forces were created from the larger Task Force. Each subtask force took part in the literature selection, review of the literature,

creation of the evidence tables, and creation and editing of the final review. The final draft review was then circulated to the entire Task Force for feedback, discussion, and, ultimately, approval.

Following Task Force approval, the completed systematic review was presented to the Joint Guidelines Committee (JGC) of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) for consideration and recommendation of endorsement on behalf of the CNS Executive Committee and the AANS Board of Directors. As part of the evaluation process, the JGC reviewers could provide input on the content and methodologies used to create the systematic review.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate evaluation of the selection of shunt implants for the treatment of pediatric hydrocephalus

Potential Harms

Complications associated with shunts include subdural hematoma, overdrainage, infection, development of slit ventricle syndrome, ventricular loculations, craniostomosis, shunt obstruction, shunt migration, and shunt malfunction.

Qualifying Statements

Qualifying Statements

- This clinical systematic review of and evidence-based guidelines for the treatment of pediatric hydrocephalus were developed by a physician volunteer task force. The articles contained therein are provided as an educational tool based on an assessment of current scientific and clinical information as well as accepted approaches to treatment. They are not intended to be a fixed protocol because some patients may require more or less treatment. Patient care and treatment should always be based on a clinician's independent medical judgment given individual clinical circumstances. The information in the guidelines reflects the current state of knowledge at the time of the project's completion. The presentations are designed to provide an accurate review of the subject matter that is covered. These guidelines are disseminated with the understanding that the recommendations of the authors and consultants who have collaborated in their development are not meant to replace individualized care and treatment advice from patients' physicians. If medical advice or assistance is required, the services of a competent physician should be sought.
- The proposals contained in these guidelines may not be suitable for use in all circumstances. The choice to implement any particular recommendation contained in these guidelines must be made by a managing physician in light of each patient's particular situation and on the basis of existing resources.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Safety

Identifying Information and Availability

Bibliographic Source(s)

Baird LC, Mazzola CA, Auguste KI, Klimo P Jr, Flannery AM. Pediatric hydrocephalus: systematic literature review and evidence-based guidelines. Part 5: Effect of valve type on cerebrospinal fluid shunt efficacy. *J Neurosurg Pediatr.* 2014 Nov;14 Suppl 1:35-43. [44 references]
[PubMed](#)

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2014 Nov

Guideline Developer(s)

American Association of Neurological Surgeons - Medical Specialty Society

Congress of Neurological Surgeons - Professional Association

Source(s) of Funding

The systematic review and evidence-based guidelines were funded exclusively by the Congress of Neurological Surgeons (CNS) and American Association of Neurological Surgeons (AANS) Pediatric Section, which received no funding from outside commercial sources to support the development of this document.

Development of this review was editorially independent from the funding agencies. The funding agencies' review of these guideline papers, following Joint Guidelines Committee (JGC) approval but prior to submission for publication, was limited to whether to endorse or reject the body of work.

Guideline Committee

Pediatric Hydrocephalus Systematic Review and Evidence-Based Guidelines Task Force

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Conflict(s) of Interest

None. All Task Force members declared any potential conflicts of interest prior to beginning work on this evidence review.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the [Journal of Neurosurgery: Pediatrics Web site](#) .

Availability of Companion Documents

The following are available:

- Flannery AM, Mazzola CA, Klimo P Jr, Duhaime AC, Baird LC, Tamber MS, Limbrick DD Jr, Nikas DC, Kemp J, Post AF, Auguste KI, Choudhri AF, Mitchell LS, Buffa D. Foreword: pediatric hydrocephalus: systematic literature review and evidence-based guidelines. *J Neurosurg Pediatr*; 2014 Nov;14 Suppl 1:1-2. Available from the [Journal of Neurosurgery: Pediatrics Web site](#) .
- Flannery AM, Mitchell L. Pediatric hydrocephalus: systematic literature review and evidence-based guidelines. Part 1: introduction and methodology. *J Neurosurg Pediatr*; 2014 Nov;14 Suppl 1:3-7. Available from the [Journal of Neurosurgery: Pediatrics Web site](#) .
- JNS pediatrics supplement: pediatric hydrocephalus systematic literature review and evidence-based guidelines. Podcast. 2014 Nov 1. Available from the [Journal of Neurosurgery Web site](#) .
- Guideline development methodology: endorsed by the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), and the AANS/CNS Joint Guideline Committee. 2012 Feb. 12 p. Available from the [Congress of Neurological Surgeons Web site](#) .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on September 17, 2015. The information was not verified by the guideline developer.

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